5 510 (k) Summary

Submitter:
Medviso AB
Thulehemsvägen 157
SE-224 67 Lund, Sweden
+46-76-1836442

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Contact Person(s):
Einar Heiberg, President
+46-76-1836442
einar@medviso.com

Device Trade Name:
Segment (**Segment**)

Device Common Name:
Cardiovascular image analysis software

Classification Name:
Class II – System, Image Processing

Product Code / Regulation Number:
LLZ / 892.2050

Substantially Equivalent To:
MRI-MASS and MRI-FLOW
Medis Medical Imaging Systems BV
Schuttersveld 9
2316 XG Leiden
The Netherlands

Device Description:

Segment is a software for analysis of cardiovascular MR images. **Segment** provides clinical quantitative data by analyzing multi-slice, multi-phase DICOM compatible cardiovascular MR images. Functional and blood flow analysis is performed using 2D, 3D and 4D data sets using standard algorithms and user input. MR images may be imported from various sources including images stored on portable media, network storage devices, PACS, and other vendor systems and supports cardiovascular MR images from all of the major MRI scanner vendors. **Segment** can be used for quantitative and qualitative analysis of cardiovascular MR images.

Intended Use:

Segment is a software that analyzes DICOM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. **Segment** specifically analyzes the function of the heart and its major vessels using multi-slice, multi-frame and velocity encoded MR images. It provides clinically relevant and reproducible data for supporting the evaluation of the function of the chambers of the heart such as left and right ventricular volumes, ejection fractions, stroke volumes, peak ejection and filing rates, myocardial mass, regional wall thickness, fractional thickening and wall motion. It also provides quantitative data on blood flow and velocity in the arterial vessels and at the heart valves. **Segment** is tested on MR images acquired from both 1.5 T and 3 T MR scanners. The data produced by **Segment** is intended to be used to support qualified cardiologist, radiologist or other licensed professional healthcare practitioners for clinical decision making. **It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.**

Technological Comparison to Predicate Device:

The proposed and predicate devices are both devices that can be used for the analysis of multi-slice, multi-frame and phase encoded DICOM-compliant MR image data sets. Both complete their analysis of these data sets using standard algorithms and user inputs to delineate the myocardial and arterial vascular wall from surrounding tissue and blood (wall contours.) Both render wall contours either fully automatically, semi-automatically, manually or in combination providing clinically relevant data. Both devices allow user input to recalculate rendered numeric output based on a qualified user's expertise. The proposed and predicate device can be operated from a personal computer. **Segment** has substantially equivalent features and specifications to the predicate device.

Laboratory and Clinical Testing:

Segment is a software intended for analyzing DICOM-compliant cardiovascular images acquired from MRI scanners. **Segment** does not in any way alter the images. Images from MRI scanners have been proven and accepted clinically.

Segment is used for image analysis and quantification of cardiovascular images providing clinically relevant numeric computations that support a cardiologist or radiologist in their diagnosis of heart disease. **Segment** contains no image digitizers and uses only lossless compression. On this basis, Medviso AB believes that clinical investigation is not necessary.

Extensive testing of the software package is performed by programmers, by non-programmers, quality assurance staff and by potential customers prior to commercial release (see Section 16.9). We conclude that the subject device, **Segment** is as safe and effective as the predicate device and posses no new questions of safety and effectiveness.

Adverse Affects on Health:
The potential hazards are identified in the Hazard Analysis (section 16.3) and are controlled by:

- Designing controls directed at the cause and/or
- Introducing protective measures and/or
- Warning the Users

All identified hazards are mitigated to minor levels of concern.

Summary of Safety and Effectiveness:
The intended use of **Segment** is for analyzing selected DICOM-compliant cardiovascular MRI. It is a support tool that provides relevant data for the clinician that is evaluating a patient's cardiovascular system using functional data such as ejection fraction, stoke volumes and cardiac output. The image analysis provided by **Segment** makes the images more clinically useful for the physician in making his diagnosis. **Segment** does **not** in any way alter the MRI imaging data in the analytical process. **Segment** provides assistance to a professionally trained physician and all of the information is subject to his/her oversight and control. Any potential hazard and /or reduction in effectiveness that may be due to the failure of the hardware or software components of **Segment** will be mitigated by the user of the device.
Segment runs on standard PC hardware and Microsoft Windows XP or Microsoft Windows Vista operating system software. The use of these industry standard components provide for maximum availability and reliability making **Segment** more effective for its intended use. The predicate device also uses standard PC hardware and another industry standard operating system, UNIX. The current versions of these industry standard products used for the operation **Segment** are of greater effectiveness and any safety concerns caused by failure of the off-the-shelf components and the **Segment** software component are no greater than the predicate device.

See Substantial Equivalence Chart in Section 12 and copies of the 510(k) Premarket Notification summaries for the predicate devices in Appendices F and G for comparison to the intended use **Segment** and discussions of hazard and safety concerns.

Conclusions:

We conclude that the subject device **Segment** is as safe and effective as the predicate device and poses no new questions of safety and effectiveness. **Segment** performs in accordance with its intended use as well as the Medis MRI-MASS and MRI-FLOW cardiovascular MRI image analysis products currently on the market. Medviso AB considers the features of the **Segment** to be substantially equivalent to the subset of features in common with the MRI-MASS (510(k) 994283) and MRI-FLOW (510(k) 994282)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2009

Mr. Einar Heiberg
President, CEO
Medviso
Thulehemsvagen 157
Lund SE-224 67
SWEDEN

Re: K090833
Trade/Device Name: Segment / Image Processing System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 18, 2009
Received: March 26, 2009

Dear Mr. Heiberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use

Indications for Use Statement

510(k) Number (if known): K090833

Device Name: Segment / Image Processing System

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090833